

PCT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 15 May 2001 (15.05.01)	
International application No. PCT/GB00/03373	Applicant's or agent's file reference PA9948-PCT
International filing date (day/month/year) 01 September 2000 (01.09.00)	Priority date (day/month/year) 03 September 1999 (03.09.99)
Applicant ROWLEY, Neil, J. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

12 March 2001 (12.03.01)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

9/9/42/7

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

CANNING, Lewis, Reuben
Amersham plc
Amersham Laboratories
White Lion Road
Amersham, Buckinghamshire HP7 9LL
ROYAUME-UNIRECEIVED
MAR 11 2002
TC 370 MAIL ROOM

Date of mailing (day/month/year) 04 February 2002 (04.02.02)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference PA9948-PCT	
International application No. PCT/GB00/03373	International filing date (day/month/year) 01 September 2000 (01.09.00)

1. The following indications appeared on record concerning:

☒ the applicant
 ☐ the inventor
 ☐ the agent
 ☐ the common representative

Name and Address NYCOMED AMERSHAM PLC Amersham Laboratories White Lion Road Amersham, Buckinghamshire HP7 9LL United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No. +44 1494 545064	
	Facsimile No. +44 1494 543977	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☒ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

Name and Address AMERSHAM PLC Amersham Laboratories White Lion Road Amersham, Buckinghamshire HP7 9LL United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No. +44 1494 545064	
	Facsimile No. +44 1494 543977	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer R. Raissi Telephone No.: (41-22) 338.83.38
---	---

PATENT COOPERATION TREATY

RECEIVED

10/069690 8 DEC 2001

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:		DUE DATE: N/A		NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)	
Canning, L.		FORMALITIES: JH ✓			
NYCOMED AMERSHAM PLC		PAT. OFF: LRC			
White Lion Road		ON DB: 31/12/01			
Amersham, Bucks HP7 9LL		CASE NO: PA9948		Date of mailing (day/month/year) 21.12.2001	
GRANDE BRETAGNE					
Applicant's or agent's file reference PA9948-PCT			IMPORTANT NOTIFICATION		
International application No. PCT/GB00/03373		International filing date (day/month/year) 01/09/2000		Priority date (day/month/year) 03/09/1999	
Applicant NYCOMED AMERSHAM PLC et al.					


1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/		Authorized officer	
 European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Senkel, H Tel. +49 89 2399-8071	





PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA9948-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/03373	International filing date (day/month/year) 01/09/2000	Priority date (day/month/year) 03/09/1999
International Patent Classification (IPC) or national classification and IPC A61K49/00		
Applicant NYCOMED AMERSHAM PLC et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 12/03/2001	Date of completion of this report 21.12.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hornich, E Telephone No. +49 89 2399 8721 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03373

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-10 as originally filed

Claims, No.:

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03373

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-9
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

**2. Citations and explanations
see separate sheet**

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03373

SECTION V

1. References

D1: DE 198 01 861 A

D2: US-A-5 565 248

D3: DE 296 09 958 U1 was cited in the Application

- 1.1 **D1** discloses glass containers having an *internal coating* of e.g. SiO_2 ; the coating is prepared by e.g. *plasma enhanced chemical vapour deposition (PECVD)* and *prevents the leaching* of (metal)ions from the container-material into the (liquid) content (e.g. pharmaceutical products) (abstract; p. 2, l. 7f. and 12-25; p. 3, l. 66-68; p. 4, l. 3-6, l. 45-47, l. 67f.; p. 5, l. 8-33; claims 1, 2, 3, 6, 10, 11).
- 1.2 **D2** discloses plastic / metal containers having an *internal coating* of e.g. *silica*, which is *inert* to the packaged content (safe contact with e.g. food, beverages; desorption of packaging material components into the food is diminished; impermeability to polar and non-polar substances) (abstract; col. 1, l. 1-30; col. 2, l. 28-47; col. 5, l. 26-40; claim 1, 2).
- 1.3 **D3** discloses that glass containers having an *internal coating* of SiO_2 prepared by PCVD are useful for the storage of pharmaceutical or diagnostic solutions.

2. Novelty (Art. 33(2) PCT)

Compositions comprising a *diagnostic agent* in a *container* having a *silica coating on the inner surface* (the diagnostic agent comprising a *non-radioactive metal complex* or a *hyperpolarised material*) have not yet been disclosed in the available prior art.

Novelty can therefore be **acknowledged** for the subject-matter of claims 1-9.

INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB00/03373

3. Inventive Step (Art. 33(3) PCT)

3.1 The problem to be solved, *derived from the description of the present application*, is that, when *diagnostics*, namely a *non-radioactive metal complex* or a *hyperpolarised material*, are stored in a container, metal ions from the container-material are leached into the product, which may *adversely affect* the product (impurity, toxicity and thus safety problems for products intended for human injection; promoting the co-precipitation of the product; affection of product imaging performance; increase of depolarisation of hyperpolarised material – decrease in lifetime).

3.2 In his letter of 03/12/01 in response to the written opinion, the Applicant points out 'that the problem has been stated in a way which partly anticipates the solution by identifying that metal ions leached from the glass container are the source of the problem'.

The Applicant contends that the problem would have to be formulated

'how to prevent intermittent impurity problems in diagnostic non-radioactive metal complex or hyperpolarised materials preparations pertaining to particulates in solution, batch to batch variability of unknown origin, and/or depolarisation'.

The Applicant herewith emphasizes that the **basis of the inventive step** involved in present application is the **formulation of the problem** (identification of the source underlying the problem).

However, *interactions between the container material and the content of the container* represent a **well-known problem**, and the storage of pharmaceuticals (or also food) in inert containers is a **matter of routine** in order to prevent such interactions. The skilled person would regard inert containers as a matter of course for the storage of diagnostics.

Thus, assessment of inventive step cannot be based on the identification of the problem as being obvious to the skilled person.

3.3 In any case, the solution of the present application resides in a composition comprising a *diagnostic agent* (being a **non-radioactive metal complex** or a **hyperpolarised material**) in a container which has a *silica coating on the inner surface*.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03373

3.4 Containers having an *inert silica coating on the inner surface* (in order to prevent leaching of metal ions from the container-material) for the *safe storage* of *pharmaceuticals (e.g. diagnostics (D3))*, food and beverages, however, have *already been disclosed* in the prior art (see above-cited **D1** and **D2**; citations in the application on p. 1 and 2, e.g. *DE 29609958U1=D3*), thus *already providing a solution* for the problem underlying the present application.

The storage of specific diagnostics, namely *a non-radioactive metal complex or a hyperpolarised material* in silica-coated containers in order to *prevent the adverse affection* of the diagnostics can be derived from the prior art (no unexpected effect) and thus only represents a *further possible use* of the *already known containers*.

3.5 Thus, an **inventive step** can presently **not be acknowledged** for the subject-matter of claims 1-9.

4. Industrial Applicability (Art. 33(4) PCT)

The requirements of industrial applicability are **fulfilled** for claims 1-9.

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PATENT COOPERATION TREATY 10/069690 12

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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11 DEC 2001
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Applicant's or agent's file reference PA9948-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03373	International filing date (day/month/year) 01/09/2000	Priority date (day/month/year) 03/09/1999
International Patent Classification (IPC) or national classification and IPC A61K49/00		
Applicant NYCOMED AMERSHAM PLC et al.		

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- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 12/03/2001	Date of completion of this report 21.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hornich, E Telephone No. +49 89 2399 8721 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03373

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Claims, No.:

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- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
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- ☐ the drawings, sheets:

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03373

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	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-9
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations
see separate sheet

SECTION V

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- 1.3 **D3** discloses that glass containers having an *internal coating* of SiO_2 prepared by PCVD are useful for the storage of pharmaceutical or diagnostic solutions.

2. Novelty (Art. 33(2) PCT)

Compositions comprising a *diagnostic agent* in a *container* having a *silica coating on the inner surface* (the diagnostic agent comprising a *non-radioactive metal complex* or a *hyperpolarised material*) have not yet been disclosed in the available prior art.

Novelty can therefore be **acknowledged** for the subject-matter of claims 1-9.

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3.1 The problem to be solved, derived from the description of the present application, is that, when *diagnostics*, namely a *non-radioactive metal complex* or a *hyperpolarised material*, are stored in a container, metal ions from the container-material are leached into the product, which may *adversely affect* the product (impurity, toxicity and thus safety problems for products intended for human injection; promoting the co-precipitation of the product; affection of product imaging performance; increase of depolarisation of hyperpolarised material – decrease in lifetime).

3.2 In his letter of 03/12/01 in response to the written opinion, the Applicant points out 'that the problem has been stated in a way which partly anticipates the solution by identifying that metal ions leached from the glass container are the source of the problem'.

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'how to prevent intermittent impurity problems in diagnostic non-radioactive metal complex or hyperpolarised materials preparations pertaining to particulates in solution, batch to batch variability of unknown origin, and/or depolarisation'.

The Applicant herewith emphasizes that the **basis of the inventive step** involved in present application is the **formulation of the problem** (identification of the source underlying the problem).

However, *interactions between the container material and the content of the container* represent a **well-known problem**, and the *storage of pharmaceuticals* (or also food) in inert containers is a **matter of routine** in order to prevent such *interactions*. The skilled person would regard inert containers as a matter of course for the storage of diagnostics.

Thus, assessment of inventive step cannot be based on the identification of the problem as being obvious to the skilled person.

3.3 In any case, the solution of the present application resides in a composition comprising a *diagnostic agent* (being a **non-radioactive metal complex** or a **hyperpolarised material**) in a container which has a *silica coating on the inner surface*.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03373

- 3.4 Containers having an *inert silica coating on the inner surface* (in order to prevent leaching of metal ions from the container-material) for the *safe storage* of *pharmaceuticals (e.g. diagnostics (D3))*, food and beverages, however, have *already been disclosed* in the prior art (see above-cited **D1** and **D2**; citations in the application on p. 1 and 2, e.g. *DE 29609958U1=D3*), thus *already providing a solution* for the problem underlying the present application.

The storage of specific diagnostics, namely *a non-radioactive metal complex or a hyperpolarised material* in silica-coated containers in order to *prevent the adverse affection* of the diagnostics can be derived from the prior art (no unexpected effect) and thus only represents a *further possible use* of the *already known containers*.

- 3.5 Thus, an **inventive step** can presently **not be acknowledged** for the subject-matter of claims 1-9.

4. Industrial Applicability (Art. 33(4) PCT)

The requirements of industrial applicability are **fulfilled** for claims 1-9.

INTERNATIONAL SEARCH REPORT

Int. Application No

PCT/GB 00/03373

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K49/00 A61K49/04

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K C03C C23C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, CHEM ABS Data, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 565 248 A (PLESTER GEORGE ET AL) 15 October 1996 (1996-10-15) abstract column 2, line 25-35 column 5, line 25-40	1,2,4-6, 9-11,14
X	DE 198 01 861 A (SCHOTT GLAS) 22 July 1999 (1999-07-22) abstract	1,2,4-6, 9-11,14
A	WO 96 26163 A (ELF ATOCHEM VLISSINGEN BV ;HOEKMAN LEENDERT CORNELIS (NL); CARSON) 29 August 1996 (1996-08-29) abstract; claim 13	1,2,4-6, 9-11,14

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

20 June 2001

Date of mailing of the international search report

27/06/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Gonzalez Ramon, N

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/03373

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5565248 A	15-10-1996	BR 9505647 A	16-01-1996
		EP 0693137 A	24-01-1996
		JP 9508966 T	24-09-1996
		NO 954008 A	09-10-1995
		WO 9521948 A	17-08-1995
		ZA 9501047 A	02-05-1996
DE 19801861 A	22-07-1999	FR 2773796 A	23-07-1999
		IT T0990035 A	20-07-1999
		JP 11278868 A	12-10-1999
		US 6200658 B	13-03-2001
WO 9626163 A	29-08-1996	AU 4849096 A	11-09-1996
		BR 9607269 A	15-12-1998
		CA 2211940 A	29-08-1996
		CN 1175935 A	11-03-1998
		CZ 9702604 A	14-01-1998
		EP 0810980 A	10-12-1997
		HU 9801366 A	28-08-1998
		JP 11504610 T	27-04-1999
		NO 973829 A	20-08-1997
		NZ 302437 A	27-04-1998
		PL 321863 A	22-12-1997
		TR 9700841 T	21-02-1998
		ZA 9601390 A	16-07-1996